

EXPEDITED PROCEDURE
 RESPONSE UNDER 37 C.F.R. § 1.116
 GROUP ART UNIT 1636

RECEIVED
 JUN 13 2002
 TECH CENTER 1800/2900

Docket No. 17668-A7-B/JPW/GJG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Axel et al.
 Serial No.: 08/484,136 Examiner: J. Ketter
 Filed : June 7, 1995 Group Art Unit: 1636
 For : METHOD OF PRODUCING PROTEINACEOUS MATERIALS

32/I
 AF/NE
 E. Williams
 7/11/02
 ENTERED
 7/11/02
 H/L

1185 Avenue of the Americas
 New York, New York 10036
 June 13, 2002

BY HAND

Examiner James Ketter
 1911 South Clark Street
 Crystal Mall 1
 7th Floor
 Arlington, VA 22202

SIR:

AMENDMENT UNDER 37 C.F.R. § 1.116

IN RESPONSE TO MAY 6, 2002 FINAL OFFICE ACTION

This is an Amendment in response to the May 6, 2002 final Office Action issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the May 6, 2002 final Office Action is due August 6, 2002. Accordingly, this Amendment is being timely filed.

Please amend the subject application as follows:

In the Claims

Please cancel claims 126-130, 133, 134 and 136-139 without prejudice or disclaimer of the subject matter of these claims.

Please amend claims 140 and 141 under 37 C.F.R. § 1.121(c). A clean version of amended claims 140 and 141 appears below, and the amendments to claims 140 and 141 are shown in the marked up

CU 02293

I

OK

TO

ENTERED

7/11/02

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 2

version of the claims attached hereto.

I'
~~140.~~¹ (Twice Amended) A transformed Chinese Hamster Ovary cell comprising a DNA construct comprising DNA I encoding a proteinaceous material foreign to the Chinese Hamster Ovary cell and linked thereto DNA II encoding an amplifiable dominant selectable phenotype not expressed by such Chinese Hamster Ovary cell prior to transformation with the construct, the construct being effective for producing the proteinaceous material when the construct is introduced into the Chinese Hamster Ovary cell, wherein the construct is stably incorporated into the chromosomal DNA of the transformed Chinese Hamster Ovary cell.

~~141.~~² (Twice Amended) A method of producing a proteinaceous material which comprises culturing transformed Chinese Hamster Ovary cells according to claim ~~140~~¹ under suitable conditions to produce the proteinaceous material and recovering the proteinaceous material so produced.

98
CU 02294
I

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 3

REMARKS

Claims 126-131, 133, 134 and 136-158 are pending in the subject application. By this Amendment, applicants have canceled without prejudice claims 126-130, 133, 134 and 136-139, and amended claims 140 and 141. Accordingly, claims 131 and 140-158 are pending in the subject application.

Allowable Subject Matter

On page 2 of the May 6, 2002 final Office Action, the Examiner indicated that claims 131 and 142-158 are allowed, and that claim 140 would be allowable if rewritten in independent form including all of the limitations of its base claim.

By this Amendment, applicants have amended claim 140 to include all of the limitations of its base claim. Accordingly, amended claim 140 should be allowed.

Applicants have also amended claim 141 to depend on allowed claim 140. Thus, claim 141 should also be allowed because it incorporates all of the limitations of an allowed base claim.

Furthermore, applicants have cancelled rejected claims 126-130, 133, 134 and 136-139 without prejudice or disclaimer of the subject matter of these claims.

Thus, claims 131 and 140-158 remain pending in the subject application, of which 131 and 142-158 have been allowed in the May 6, 2002 final Office Action, and claims 140 and 141 should be allowed as amended.

With respect to the rejections set forth in the May 6, 2002 final Office Action, applicants' cancellation of the rejected claims has made the rejections moot. However, applicants point out for

CU 02295

I

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 4

the record that the rejected claims have been cancelled solely to advance the subject application to issuance, without acknowledging the correctness of the Examiner's rejections.

In conclusion, applicants respectfully request an expeditious issuance of a Notice of Allowance for pending claims 131 and 140-158 in the subject application.

Supplemental Information Disclosure Statement

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants point out to the Examiner that a Notice of Allowance was issued May 6, 2002 in copending U.S. Serial No. 08/477,159, filed June 7, 1995 (previously disclosed in the Information Disclosure Statement filed April 17, 2002), and applicants have paid the issue fee in connection therewith on May 14, 2002.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

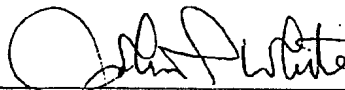
CU 02296

I

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 5

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

CU 02297

I

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 6

**Marked-Up Version of Amended
Claims Pursuant to 37 C.F.R. §1.121(c)**

- ~~126. A DNA construct for expression in eucaryotic cells comprising DNA I encoding a proteinaceous material foreign to such eucaryotic cells and linked thereto DNA II encoding an amplifiable dominant selectable phenotype not expressed by such eucaryotic cells prior to transformation with the construct, the construct being effective for producing the proteinaceous material when the construct is introduced into such eucaryotic cells.~~
- ~~127. A DNA construct of claim 126 for expression in mammalian cells.~~
- ~~128. A DNA construct of claim 127 for expression in Chinese Hamster Ovary cells.~~
- ~~129. A DNA construct of claim 126, wherein the proteinaceous material is an interferon, insulin, a growth hormone, a clotting factor, a viral antigen, an antibody, or an enzyme.~~
- ~~130. A DNA construct of any of claims 126-129, wherein DNA II encodes a dihydrofolate reductase which renders such eucaryotic cells resistant to methotrexate.~~
131. A DNA construct for expression in Chinese Hamster Ovary (CHO) cells comprising DNA I encoding a proteinaceous material foreign to such CHO cells and linked thereto DNA II encoding a dihydrofolate reductase which is not expressed by such CHO cells and renders such CHO cells resistant to methotrexate when the CHO cells are transformed with the construct, the construct being

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 7

effective for producing the proteinaceous material when the construct is introduced into such CHO cells.

~~133. The DNA construct of claim 126 for expression in plant cells.~~

~~134. The DNA construct of claim 126 for expression in yeast cells.~~

~~136. The DNA construct of claim 126, wherein the proteinaceous material is a glycoprotein.~~

~~137. A transformed eucaryotic cell comprising the DNA construct of claim 126 stably incorporated into the chromosomal DNA of the transformed eucaryotic cell.~~

~~138. A transformed plant cell comprising the DNA construct of claim 133 stably incorporated into the chromosomal DNA of the transformed plant cell.~~

~~139. A transformed mammalian cell comprising the DNA construct of claim 127 stably incorporated into the chromosomal DNA of the transformed mammalian cell.~~

140. (Twice Amended) A transformed Chinese Hamster Ovary cell comprising the a DNA construct of claim 128 comprising DNA I encoding a proteinaceous material foreign to the Chinese Hamster Ovary cell and linked thereto DNA II encoding an amplifiable dominant selectable phenotype not expressed by such Chinese Hamster Ovary cell prior to transformation with the construct, the construct being effective for producing the proteinaceous material when the construct is introduced into the Chinese Hamster Ovary cell, wherein the

CU 02299

1

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 8

construct is stably incorporated into the chromosomal DNA of the transformed Chinese Hamster Ovary cell.

141. (Twice Amended) A method of producing a proteinaceous material which comprises culturing transformed Chinese Hamster Ovary cells ~~of any of claims 137-140~~ according to claim 140 under suitable conditions to produce the proteinaceous material and recovering the proteinaceous material so produced.
142. A transformed Chinese Hamster Ovary (CHO) cell which comprises amplified foreign DNA I encoding a proteinaceous material and amplified DNA II encoding a dihydrofolate reductase not expressed by the transformed CHO cell prior to transformation, both DNA I and DNA II being stably incorporated into the chromosomal DNA of the transformed CHO cell.
143. The transformed Chinese Hamster Ovary cell of claim 142, wherein the proteinaceous material is a glycoprotein..
144. A transformed Chinese Hamster Ovary (CHO) cell which comprises amplified foreign DNA I corresponding to a gene of interest which encodes a proteinaceous material and amplified DNA II encoding a dominant selectable phenotype not expressed by the transformed cell prior to transformation, DNA I or DNA II or both being attached to bacterial plasmid DNA or phage DNA, and both DNA I and DNA II being stably incorporated into the chromosomal DNA of the transformed cell.
145. The transformed CHO cell of claim 144, wherein DNA II encodes a dihydrofolate reductase which renders the

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 9

transformed CHO cell resistant to methotrexate.

146. A method of producing a proteinaceous protein which comprises culturing transformed CHO cells of claim 144 under suitable conditions to produce the proteinaceous material and recovering the proteinaceous material so produced.
147. The method of claim 146, wherein the proteinaceous material is glycoprotein.
148. The transformed Chinese Hamster Ovary cell of claim 144, wherein the DNA I is attached to bacterial plasmid DNA.
149. The transformed Chinese Hamster Ovary cell of claim 144, wherein the DNA II is attached to bacterial plasmid DNA.
150. The transformed Chinese Hamster Ovary cell of claim 144, wherein both DNA I and DNA II is attached to bacterial plasmid DNA.
151. The transformed Chinese Hamster Ovary cell of claim 144, wherein the DNA I is attached to phage DNA.
152. The transformed Chinese Hamster Ovary cell of claim 144, wherein the DNA II is attached to phage DNA.
153. The transformed Chinese Hamster Ovary cell of claim 144, wherein both DNA I and DNA II is attached to phage DNA.
154. A transformed Chinese Hamster Ovary (CHO) cell which comprises amplified foreign DNA I corresponding to a gene encoding a glycoprotein of interest and amplified DNA II

Applicants: Richard Axel et al.
Serial No.: 08/484,136
Filed : June 7, 1995
Page 10

encoding a dominant selectable phenotype not expressed by the transformed CHO cell prior to transformation, and both DNA I and DNA II being stably incorporated into the chromosomal DNA of the transformed Chinese Hamster Ovary cell.

155. The transformed Chinese Hamster Ovary cell of claim 154, wherein DNA II encodes a dihydrofolate reductase which renders the transformed cell resistant to methotrexate.
156. The transformed Chinese Hamster Ovary cell of claim 154, wherein DNA I or DNA II or both DNA I and DNA II is attached to bacterial plasmid DNA or phage DNA.
157. The transformed Chinese Hamster Ovary cell of any of claims 154-156, further comprising the glycoprotein of interest.
158. The transformed Chinese Hamster Ovary cell of any of claims 144, 145 and 148-153, further comprising the proteinaceous material.